K003026

JUN 1 9 2001

510(k) Summary
PFC Sigma Lugged Tibial Tray

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

A. Contact Person:

Janet G. Johnson, RAC
Group Leader, Regulatory Submissions
(219) 371-4907

B. Device Information:

Proprietary Name:	PFC Sigma Lugged Tibial Tray
Common Name:	Tibial Tray
Classification Name:	Knee Joint Patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II, per 21 §CFR 888.3560
Product Code:	87 JWH

C. Indications for Use:

The PFC Sigma Lugged Tibial Tray is intended to provide increased mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Candidates for total knee replacement include elderly patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total unicondylar knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

Caution: This knee prosthesis component is intended for cemented use only.

D. Device Description:

The PFC Sigma Lugged Tibial Tray is designed with four angled pegs to provide firm fixation and anti-rotational properties while preserving bone stock. It is manufactured from titanium alloy (Ti-6Al-4V) and the distal surface is coated with commercially pure titanium porous coating to enhance cement fixation. If additional fixation is required, the tibial tray is designed with one screw hole to accept a bone screw.

The PFC Sigma Lugged Tibial Tray is designed for use with both P.F.C. Modular and P.F.C. Sigma tibial inserts, including curved, posterior lipped and stabilized.

E. Substantial Equivalence:

The PFC Sigma Lugged Tibial Tray is substantially equivalent in terms of intended use, materials, design, sterilization method, and packaging to the Trick Modular Knee Tibial Tray –Porous (K931054) and the P.F.C. Sigma Porous Modular Keel Tibial Tray (K991106).

The determination of substantial equivalence for this device was based on a detailed device description, and conformance with voluntary performance standards, e.g. ASTM F-1580, and ASTM F1044.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Ms. Janet G. Johnson, RAC
Group Leader, Regulatory Submissions
Depuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K003026
Trade Name: PFC Sigma Lugged Tibial Tray
Regulation Number: 888.3560
Regulatory Class: II
Product Code: JWH
Dated: March 23, 2001
Received: March 26, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known) K003026

Device Name PFC Sigma Lugged Tibial Tray

Indications for Use

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Caution: This knee prosthesis component is intended for cemented use only.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003026

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)